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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,026	06/26/2003	Grant Peterson	F-5933	5607

7590 05/05/2006

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/607,026		PETERSON ET AL.	
	Examiner		Art Unit	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/24/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by 6,761,704 to Crawford.

In the specification and figures, Crawford discloses the apparatus as claimed by applicant. In particular, Crawford discloses a needle assembly 12 comprising a hub 20 with a first threaded end (at 14) and a second ribbed end (at 16) and an internal lumen 30 therethrough (see FIG 3, column 4, lines 50-67, column 5, lines 1-15). First end comprises cannula 26 terminating in blunt tip 28. Second end comprises cannula 22 with a sharpened puncturing tip 24. The central hub further comprises shoulders or fins 16 on one side and threads 14 on the other:

With regard to applicant's recitation drawn to the attachment of the needle assembly to a barrel, Crawford discloses that the needle assembly is adapted for attachment to a separate needle holder 110, 112, as is well-known in the art (see column 4, lines 51-59, FIGS 5-6):

With regard to claim 3, Crawford discloses that the needle assembly may be made from polyethylene, which is a thermoplastic material.

With regard to claim 7, Crawford discloses that the needle assembly may be provided with needle covers for the first and second needle ends (see column 8, lines 1-20).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,761,704 to Crawford, as applied above, in view of US 6,726,649 to Swenson.

In the specification and figures, Crawford discloses the device substantially as claimed by applicant. In particular, Crawford discloses that the device may be comprised of thermoplastics such as polyethylene. Crawford fails to disclose that the desired polymers include polypropylene. Swenson discloses that his needle assembly may be made of various rigid polymers, including polypropylene (see column 5, lines 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use polypropylene to construct the needle assembly disclosed by Crawford, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

5. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,495,855 to Dudar et al in view of US 6,761,704 to Crawford.

In the specification and figures, Dudar discloses the apparatus substantially as claimed by applicant with the exception of a flexible sleeve over the sharpened piercing tip. In particular, Dudar discloses a connector 10 with a first end 16 with a blunt cannula 26, second end 14 with a pointed needle, and a passage that allows blood flow from cannula to the needle end (see, generally, column 4). The piercing member 12 may be covered by needle tip protector 42. Dudar fails to disclose that the tip protector comprises a flexible sleeve.

However, Crawford discloses that the needle assembly is further provided with an elastomeric sleeve 90 that covers cannula 26 and is easily displaced when the cannulas are employed (see column 8, lines 27-30, column 9, lines 1-17). Therefore, it would have been obvious to substitute the flexible sleeve disclosed by Crawford for the needle tip protector disclosed by Dudar in order to allow the sleeve to move out of the way when using the connector assembly, as taught by Crawford.

With regard to claim 9, Dudar discloses that needle 12 may be enclosed by removable shield 18, but fails to disclose a second cap or shield for cannula 26. However, Crawford specifically discloses that his device comprises caps or covers for both ends of the cannula assembly (see Crawford column 8, lines 1-28) in order to cover and protect the cannulas. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second needle

Art Unit: 3761

protector or cap as disclosed by Crawford to the second end of the cannula assembly disclosed by Dudar in order to cover and protect the cannulas, as taught by Crawford.

With regard to claim 10, neither reference specifically teaches that the needle covers each comprise an open and a closed end, wherein the open ends face one another. However, caps designed to cover needle assemblies generally have an opening to accept the needle assembly and a closed end, otherwise the cap wouldn't act as a cover (see US 6,726,649 to Swenson, FIG 4 for reference). Therefore, it flows naturally from the teaching of the prior art to provide covers or caps for the cannula ends that the covers would comprise open ends and closed ends wherein the open ends face one another.

With regard to claim 11, Dudar discloses that needle 12 may be enclosed by removable shield 18, but fails to disclose that the hub comprises fins that engage mating slots in a needle cover. However, Crawford specifically discloses that his device comprises fins 16 that interact with needle cover (not shown) to provide a frictional fit between the shoulder and the cover, maintaining the cover in position (see column 8, lines 1-12). The specific disclosure that the cover is maintained in position, rather than being rotatable when deployed on the needle assembly, indicates that there are slots that engage with fins 16 on the hub, preventing movement of the cover. Therefore, it would have been obvious to provide the hub of the Dudar device with fins and a mating cover, as disclosed by Crawford, in order to cover and protect the cannula and maintain the cover in place, as taught by Crawford.

With regard to claim 12, Dudar specifically discloses that the connector 10 may be connected to barrel or needle holder 44 (see FIG 3, column 5, lines 10-35), wherein the sharpened tip 12/40 is located inside the barrel 44. The piercing member 12 may be covered by needle tip protector 42. Dudar fails to disclose that the tip protector comprises a flexible sleeve. However, Crawford discloses that the needle assembly is further provided with an elastomeric sleeve 90 that covers cannula 26 and is easily displaced when the cannulas are employed (see column 8, lines 27-30, column 9, lines 1-17). Therefore, it would have been obvious to substitute the flexible sleeve disclosed by Crawford for the needle tip protector disclosed by Dudar in order to allow the sleeve to move out of the way when using the connector assembly, as taught by Crawford.

Response to Arguments

6. Applicant's amendment filed 24 February 2006 has been entered and considered.

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3761

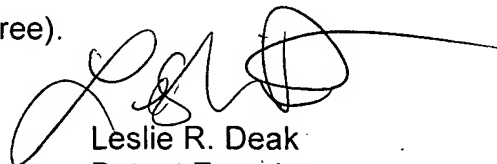
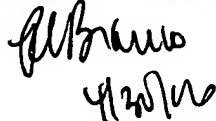
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICIA BIANCO
PRIMARY EXAMINER



Leslie R. Deak
Patent Examiner
Art Unit 3761
19 April 2006